REMARKS/ARGUMENTS

Reconsideration of this Application is respectfully requested. The present response replies to a final Office Action dated April 29, 2010. Claims 1-3, 7-12, 14, 15, and 18-32 are pending in the present application. In the Office Action, the Examiner rejected claims 1-3, 7-12, 14, 15, and 18-32 on various grounds. The Applicant responds to each ground of rejection as subsequently recited herein.

35 U.S.C. §112 Rejections

Claims 30-32 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, particularly, for not having a written basis for the new limitation that the plurality of therapeutic agents is released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded. The Applicant respectfully disagrees and asserts that the written description in the specification fully supports the limitation.

At least, the present Application recites that the timing coating is actuated when it begins to erode, and the second therapeutic agent is released after the timing coating has eroded. *See* paragraph [0038]. The timing coating is actuated when it begins to erode, and the third therapeutic agent is released after the timing coating has eroded. *See* paragraph [0040]. Further, Figure 3 clearly shows erosion of the timing coating 232, followed by release of therapeutic coating 222, erosion of the timing coating 234, followed by release of therapeutic coating 224, and erosion of the timing coating 236, followed by release of therapeutic coating 226. *See* Figure 3; paragraphs [0026]-[0033]. The erosion of the timing coating is only shown as occurring before the release of therapeutic coating, so the timing coating erodes completely before the next therapeutic coating is released.

Withdrawal of the rejection of claims 30-32 under 35 U.S.C. §112 as failing to comply with the written description requirement is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claims 12, 14, 15, and 18-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication) in view of U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan C* patent).

The Applicant respectfully asserts that the *Miller* publication and the *Sirhan C* patent publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication and the *Sirhan C* patent fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

At most, the *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more barrier layers. *See* paragraph [0052]. A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer

layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers and do not cause the therapeutic agents to be released exclusively and sequentially as claimed. A therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

At most, the *Sirhan C* patent discloses means for releasing the substance comprises a reservoir on or within the structure containing mycophenolic acid and a cover over the reservoir. The cover may be degradable or partially degradable over a preselected time period so as to provide the desired mycophenolic acid release rate. *See* column 5, lines 57-62. Further, the *Sirhan C* patent discloses a rate limiting barrier may be formed adjacent to the structure and/or the matrix. Such rate limiting barriers may be nonerodible or nondegradable, such as silicone, polytetrafluorethylene (PTFE), parylene, and PARYLAST™, and control the flow rate of release passing through the rate limiting barrier. In such a case, mycophenolic acid may be released by diffusion through the rate limiting barrier. *See* column 5, lines 25-32. Although the *Sirhan C* patent suggests a combination of multiple drugs that are individually included in different coats, where the coats may release the multiple drugs simultaneously and/or sequentially, the *Sirhan C* patent fails to disclose layers allowing each of the plurality of therapeutic coatings to be released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings as claimed.

Claims 14, 15, and 18-20 depend directly or indirectly from independent claim 12, and so include all the elements and limitations of independent claim 12. The Applicant therefore respectfully submits that dependent claims 14, 15, and 18-20 are allowable over the *Miller* publication for at least the same reasons as set forth above for independent claim 12.

Regarding claims 18 and 20, the *Miller* publication and the *Sirhan C* patent fail to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062]. At most, the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion. *See* column 5, lines 25-32, 57-62.

Withdrawal of the rejection of claims 12, 14, 15, and 18-20 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication is respectfully requested.

B. Claims 1-3, 7-12, and 19-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

The Applicant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A system for treating a vascular condition including therapeutic agents in each of the therapeutic coatings being released exclusively and sequentially upon the erosion of the overlying timing coating without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1; or

A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12; or

A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition including releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating, as recited in independent claim 23.

The *Sirhan B* publication and the *Fischell* publication also fail to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claims 2, 3, and 7-11; claims 19-22; and claims 24-29 depend directly or indirectly from independent claims 1, 12, and 23, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 2, 3, 7-11, 19-22, and 24-29 are allowable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 7, 9, and 27, the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication fail to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062]. At most, the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion. *See* column 5, lines 25-32, 57-62.

Withdrawal of the rejection of claims 1-3, 7-12, and 19-29 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, and the *Fischell* publication is respectfully requested.

C. Claims 12 and 31 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of U.S. Patent Publication No. 2004/0249449 to Shanley, *et al.* (the *Shanley* publication).

The Applicant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, and the *Shanley* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

The *Shanley* publication also fails to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claim 31 depends directly from independent claim 12 and so includes all the elements and limitations of independent claim 12. The Applicant therefore respectfully submits that dependent claim 12 is allowable over the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication for at least the same reasons as set forth above for independent claim 12.

Regarding claim 31, the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication fail to disclose each of the plurality of therapeutic agents being released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded as claimed.

Withdrawal of the rejection of claims 12 and 31 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* publication, and the *Shanley* publication is respectfully requested.

D. Claims 1, 23, 30, and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan C* patent and further in view of the *Sirhan B* publication in view of the *Fischell* publication and further in view of the *Shanley* publication.

The Applicant respectfully asserts that the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication and the *Sirhan C* patent, alone or in combination, fail to disclose, teach, or suggest:

> A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12; or
>
> A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition including releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating, as recited in independent claim 23.

The *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication also fail to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and the *Sirhan C* patent discloses a cover over the reservoir and rate limiting barriers allowing diffusion, but neither discloses sequential release of therapeutic agents as claimed.

Claims 30 and 32 depend directly from independent claims 1 and 23, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claim 12 is allowable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 30 and 32, the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication fail to disclose each of the plurality of therapeutic agents being released from the plurality of therapeutic coatings after the adjacent overlying timing coating has completely eroded as claimed.

Withdrawal of the rejection of claims 1, 23, 30, and 32 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan C* patent, the *Sirhan B* publication, the *Fischell* publication, and the *Shanley* publication is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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